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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,121	01/24/2005	Stanley George Bonney	PG4885USw	8414
23347	7590	07/07/2008		
GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B482 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			EXAMINER DIXON, ANNETTE FREDRICKA	
			ART UNIT 3771	PAPER NUMBER
			NOTIFICATION DATE 07/07/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/523,121	<b>Applicant(s)</b> BONNEY ET AL.	
	<b>Examiner</b> Annette F. Dixon	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

1. This Office Action is in response to request for continued examination filed on April 21, 2008. Examiner acknowledges claims 1-7 and 9-22 are pending in this application with claim 1 having been currently amended, and claims 8 and 23-37 having been cancelled.

### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 21, 2008 has been entered.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-7, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox et al. (6,234,167).

As to Claim 1-4, Cox discloses a medicament dispenser device (121) for use in the delivery of a multi-component combination medicament product, the device comprising: a first medicament container (37) containing a plural co-formulation compatible medicament components; a first release means for the contents first medicament container for delivery thereof (35); at least one further medicament container (137), each containing at least one co-formulation incompatible medicament component; and at least one further release means for releasing the contents of each at least one further medicament container for delivery thereof (135), wherein the at least one co-formulation incompatible medicament component is kept separate from the plural co-formulation compatible components until the point of release thereof for delivery in combination. Regarding the co-formulation limitation, Cox discloses the medicament containers may include two or more components mixed together before the material is volatilized. (Column 9, Lines 52-66 and Figure 3).

As to Claim 5 and 10, Cox discloses an aerosol generator (121) is an inhaler device. (Column 3, Lines 45-60).

As to Claim 6, Cox discloses the first medicament container and the second medicament container may be similar or different. Specifically, Cox discloses the first and second medicament container may be held at the same or different pressures to facilitate the delivery of the medicament to the patient. Thus inherently, the first medicament container may be similar to the second medicament container when the co-

formulations are held at the same pressure or the first medicament container may be different from the second medicament container when the co-formulations are held at different pressures. (Column 8, Line 47 thru Column 9, Line 12).

As to Claim 9, Cox discloses a mixing chamber (29) including a first inlet (the location between the release means 35 and element 29) for receiving the released contents of the first medicament container (37), a second inlet (the location between the release means 135 and element 29) for receiving the released contents of the second medicament container (137), and an outlet (the location between element 29 and mouthpiece 53) for the delivery of combination medicament product therefrom.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. (6,234,167) in view Marfat et al. (6,559,168).

As to Claims 11-22, Cox discloses a medicament device, yet does not expressly disclose the recited medicaments. However at the time the invention was made the use of the recited medicaments was well known. Specifically, Marfat discloses all the recited medicaments are known and used in the treatment of respiratory diseases such

as asthma, chronic bronchitis, and chronic obstructive pulmonary disease. (Column 209-256). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Cox to include the medicaments, as taught by Marfat, to be used in the treatment of respiratory diseases.

### ***Response to Arguments***

7. Applicant's arguments filed October 2, 2007 have been fully considered but they are not persuasive. Applicant asserts the prior art made of record does not disclose or teach "release means are mechanically or fairly suggest a first and second release means that are coupled together, thereby enabling simultaneous delivery of medicament from each dispenser in response to a single patient actuation step."

Examiner respectfully disagrees with Applicant's assertion. The device of Cox discloses two valves (35 and 135) capable of being utilized with simultaneously (Column 8, Lines 47-65). Regarding the mechanical coupling of the valves (35 and 135). Webster's dictionary defines "mechanically" as "of or relating to machines or tools, operated or produced by machine". Intrinsically, this definition discloses the mechanical operation of the valves (35 and 135) thru the use of the machinery of the control device (43).

Finally, regarding the "single patient actuation step", Cox discloses the signal for activation is delivered to the control device (43) via the air flow detecting device (51). (Column 5, Lines 50-62). Therefore, in light of the aforementioned reasoning, the rejection of the claims has been maintained.

***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Behar (5,169,029) discloses a simultaneous medicament dispenser.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771

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